AUG 0 5 2002

POREX
SURGICAL PRODUCTS GROUP

510(k) SUMMARY

Manufacturer and Submitter **K021357**

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

Contact: Howard Mercer, Ph.D.
e-mail: howard_mercer@porex.com

Date: April 26, 2002

Trade Name:

MEDPOR® Plus Sphere; MEDPOR® Plus COI™ (Conical Orbital Implant); MEDPOR® Plus MCOI™ (Multi-Purpose Conical Orbital Implant); MEDPOR® Plus SST™ Sphere (Smooth Surface Tunnel Sphere); MEDPOR® Plus SST™ COI™; MEDPOR® Plus MCOI™ SST™; MEDPOR® Plus QUAD™ Motility Implant

Class II Device

Substantially equivalent to:

Orbital volume replacement implants currently cleared for marketing and to Bioglass® Synthetic Bone Graft Particulate

Device description:

The devices of this submission are orbital volume replacement implants formed by blending Bioglass® Synthetic Bone Graft Particulate with the polyethylene used to produce MEDPOR® Surgical Implant Material.

Indications for Use:

MEDPOR Surgical Implants in block, sheet and preformed shapes are intended for augmentation or restoration in the craniofacial region.

Porex Surgical, Inc.
15 Dart Road • Newnan, GA 30265-1017 USA • TEL 1-800-521-7321 • 1-678-479-1610 • FAX 1-678-423-1435

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 5 2002

Porex Surgical Inc.
c/o Howard Mercer, Ph.D.
Regulatory Affairs Manager
15 Dart Road
Newnan, GA 30265

Re: K021357
Trade/Device Name: MEDPOR® Plus Orbital Volume Replacement Implant
Regulation Number: 886.3320
Regulation Name: Eye sphere implant
Regulatory Class: II
Product Code: HPZ
Dated: July 29, 2002
Received: July 30, 2002

Dear Dr. Mercer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION FOR USE

Applicant: Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

510(k) Number: **K021357**

Device Name: MEDPOR® Plus orbital volume replacement implants

MEDPOR® Plus Sphere; MEDPOR® Plus COI™ (Conical Orbital Implant); MEDPOR® Plus MCOI™ (Multi-Purpose Conical Orbital Implant); MEDPOR® Plus SST™ Sphere (Smooth Surface Tunnel Sphere); MEDPOR® Plus SST™ COI™; MEDPOR® Plus MCOI™ SST™; MEDPOR® Plus QUAD™ Motility Implant

Indications for Use:

MEDPOR Surgical Implants in block, sheet and preformed shapes are intended for augmentation or restoration in the craniofacial region.

(PLEASE DO NOT WRITE BELOW THIS LINE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021357

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21CFR801.109